, IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of

Confirmation No. 2849

Yasuyuki SUZUKI et al.

Docket No. 2002-0206A

Serial No. 10/049,821

Group Art Unit 1616

Filed February 19, 2002

Examiner Alton N. Pryor

PERCUTANEOUS ABSORPTION PREPARATIONS

SECOND SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

Pursuant to the provisions of 37 C.F.R. §§ 1.56, 1.97 and 1.98, Applicants request consideration of the references listed on attached Form PTO-1449 and any additional information identified below in paragraph 3. A legible copy of each reference listed on the Form PTO-1449 is enclosed, except a copy is not provided for:

[X]	each U.S. Patent and U.S. Patent application publication;									
0	each PCT/	reference	previousl ; and/or	y cited	in	the i	nternational	applic	ation	
0	each	reference	previously	cited in	prior	parent	application	Serial	No	

1a. [] This Information Disclosure Statement is submitted:

within three months of the filing date (or of entry into the National Stage) of the above-entitled application, <u>or</u>

before the mailing of a first Office Action on the merits or the mailing of a first Office Action after the filing of an RCE,

and thus no certification and/or fee is required.

1b. [] This Information Disclosure Statement is submitted

after the events of above paragraph 1a and prior to the mailing date of a final Office Action or a Notice of Allowance or an action which otherwise closes prosecution in the application, and thus:

- (1) [] the certification of paragraph 2 below is provided, or
- (2) [] the fee of \$180.00 specified in 37 C.F.R. § 1.17(p) is enclosed.
- 1c. [X] This Information Disclosure Statement is submitted:

after the mailing date of a final Office Action or Notice of Allowance or action which otherwise closes prosecution in the application, and prior to payment of the issue fee, and thus:

the certification of paragraph 2 below is provided, and

the fee of \$180.00 specified in 37 C.F.R. § 1.17(p) is enclosed.

2. It is hereby certified

- a. [X] that each item of information contained in this Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the Statement, or
- b. [] that no item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application and, to the knowledge of the person signing the certification after making reasonable inquiry, was known to any individual designated in §1.56(c) more than three months prior to the filing of the Statement.
- 3. [] Consideration of the following list of additional information (including any copending or abandoned U.S. application, prior uses and/or sales, etc.) is requested.

- For each non-English language reference listed on the attached Form PTO-1449, reference 4. is made to:
 - a. [] a full or partial English language translation submitted herewith,
 - b. [] a foreign patent office search report (in the English language) submitted herewith,
 - the concise explanation contained in the specification of the present application at c. [] page,
 - the concise explanation set forth in the attached English language abstract, d. []
 - e. [] the concise explanation set forth below or on a separate sheet attached to the reference:
- 5. [X] A Supplementary Partial European Search Report, dated January 31, 2005, citing one or more of the references is enclosed.
- 6. [] <u>Statement Under 37 C.F.R. § 1.704(d)</u>

Each item of information contained in the Information Disclosure Statement was first cited in any communication from a foreign Patent Office in a counterpart application, and this communication was not received by any individual designated in §1.56(c) more than thirty days prior to the filing of the Information Disclosure Statement.

Respectfully submitted,

Yasuyuki SUZUKI et al.

By Warren M. Cheek, Jr. (

Registration No. 33,367

Attorney for Applicants

WMC/JFW/ksh Washington, D.C. 20006-1021 Telephone (202) 721-8200 Facsimile (202) 721-8250 February 22, 2005

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FORM PTO 1449 (modified) U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE LIST OF REFERENCES CITED BY APPLICANT(S) (Use several sheets if necessary) Date Submitted to PTO: February 22, 2005				ATTY DOCKET NO. 2002-0206A SERIAL NO. 10/049,821				PEC	\		
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	AO B-J Lee et al., "Solubility and Stability of Melatonin in Propylene glycol and 2-Hydroxypropyl-β-cyclodextrin Vehicles", Arch. Pharm. Res., Vol. 20, No. 6, pp. 560-565, 1997.										
	AP	B-J Lee, "Development and Evaluation of an Oral Controlled Release and a Transdermal Delivery System for Melatonin in Human Subjects", Dissertation Abstracts International, Vol. 54, No. 2, pp. 762-763, 1993.									
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^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.